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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,846	10/23/2003	Donald K. Jones	CRD5035CIP1	6702
27777	7590	09/28/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/691,846

Applicant(s)

JONES ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/29/05</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 requires that the anchor members be interlocked in a gap between the proximal and distal cylindrical members. This is not sufficiently supported, because the specification only states that the proximal and distal cylindrical members act as stops to prevent longitudinal movement of the entire stent:

*"The proximal and distal cylindrical members 16, 18 are spaced apart to form a gap between the cylindrical member and serve as stop members extending radially outward from the core wire 14 to engage the stent 20 in order to prevent longitudinal movement of the stent relative to the core wire 14." (page 8, line 20 through page 9, line 3)*

Since the entire stent lies in the gap formed between the proximal and distal cylindrical members, there is really no "interlock" between the anchor members and the gap formed between proximal and distal cylindrical members.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states that the anchor members are "interlocked" within the gap formed between the proximal and distal cylindrical members. This is unclear, because the specification states in lines 10-15 of page 10 that *"the anchor members (52) align with and are disposed within the **first gap 42**, thus coupling the stent to the elongated core wire 14."* While the instant application fails to further explain the first gap, the parent case (Application number 10/651,569) states that the **first gap 42** is formed between the proximal and intermediate cylindrical members (page 8, lines 9-11). Applicant states that the proximal and distal cylindrical members only act as stops to prevent longitudinal movement of the entire stent:

*"The proximal and distal cylindrical members 16, 18 are spaced apart to form a gap between the cylindrical member and serve as stop members extending radially outward from the core wire 14 to engage the stent 20 in order to prevent longitudinal movement of the stent relative to the core wire 14."* (page 8, line 20 through page 9, line 3)

Since the entire stent lies in the gap formed between the proximal and distal cylindrical members, there is really no "interlock" between the anchor members and the proximal and distal cylindrical members.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. in view of U.S. Patent No. 5,919,225 to Lau et al.

Hayashi discloses a self-expanding vascular graft, or stent, delivery system in Figures 4, 5A, 5B that includes an elongated core (20) member, a self-expanding graft (15), and actuatable retaining rings (127) disposed around the graft (15). In lines 17-20 of column 3, Hayashi explains that a conventional catheter may be used with the delivery system, where the core member (20) and graft (15) would be slidably disposed within its lumen. Electrical conductors (25,26) are connected to resistive heating elements (129,130) that are positioned near the retaining rings (127). In lines 45-53 of column 3, Hayashi explains that the retaining rings (127) are severed by heat supplied by the resistive heating elements (129,130) to allow the self-expanding graft (15) to expand. Figure 5B clearly illustrates the severed retaining rings (127). Hayashi explains that the graft, or stent, may be woven (column 4, line 35). A woven structure inherently comprises a plurality of cells formed by a plurality of strut members. As best illustrated in Figures 4 and 5A, proximal and distal "anchor members" (130) are passed through the stent. Since they contact the stent, they are considered to meet the broad limitation "*placed on a strut member.*" The retaining ring is positioned at the anchor member (130) for retaining the stent on the core member.

Hayashi lacks proximal and distal cylindrical members disposed on the core member. Lau et al. discloses a stent delivery system in Figures 19A-C that includes a core member (318) with both proximal and distal cylindrical members (322 and 320) attached to the core member (318). Lau teaches that the cylindrical members (320,322) hold the stent (312) axially in place on the core member (318) prior to deployment (column 18, lines 16-19). The gap defined between the members (320,322) is at least as long as the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include proximal and distal cylindrical members on the core member of Hayashi, as taught by Lau, as this provides barriers that hold the graft, or stent, axially in place relative to the core member prior to deployment. The stent is considered to be "interlocked" in this gap.

4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Lau, as applied to claim 5 above, and further in view of Barry.

Hayashi, as modified by Lau and Goicoechea above, includes all the limitations of claims 6-8 except for the retaining ring being a hot melt polymer filament. Hayashi does state that the retaining rings should be made from suture material (column 4, line 26), which includes many types of polymer filaments. Barry discloses another type of delivery system, in which an electric current is supplied to a resistive heating element. The heat is used to sever a coupling, thereby releasing a vascular implant. Here, Barry teaches that the coupling material can be a hot melt adhesive (which is inherently a polymer), because this type of material softens and yields when exposed to heat. (See column 4, lines 29 – 40.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the retaining filaments of Hayashi from a hot melt polymeric material, as taught by Barry, as this material is

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suitable for forming retaining elements that yield with the application of heat in a vascular implant delivery system.

### ***Response to Arguments***

5. Applicant's arguments filed 7/25/05 have been fully considered but they are not persuasive. On page 6 of the arguments, applicant states, "*the proximal anchor members (52) have been retained in the gap just to the right of the tubular member (16).*"

This is found improper, as discussed above under 112, because the specification fails to describe the first gap (42) formed between the proximal and intermediate cylindrical members, as set forth in the parent application (10,651,569). This application simply states that the proximal and distal cylindrical members act as stops. Since the entire stent lies within this gap, no "interlocking" of the anchor members is possible.

6. Upon reconsideration of the art, the broad limitation "*anchor member placed on one of said plurality of strut members*" is met by the anchoring structures (130) provided by Hayashi that pass through the stent and into contact with the retaining rings.

7. Applicant's arguments with respect to Goicoechea have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

9/21/05

*SKW*  
*John M. Woo*